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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,514	11/01/2004	Hoon Choi	1599-0269PUS1	8899

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PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

SEAMAN, D MARGARET M

ART UNIT	PAPER NUMBER
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1625

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/28/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/28/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/510,514

Applicant(s)

CHOI ET AL.

Examiner

D. Margaret Seaman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

This application was filed 1 November 2004 and is a 371 of PCT/KR03/00683 (4 April 2003) which claims priority to Korea 10-2002-0018847 (8 April 2002). RCE papers were filed 2/28/2007. Claims 1-13 are before the Examiner.

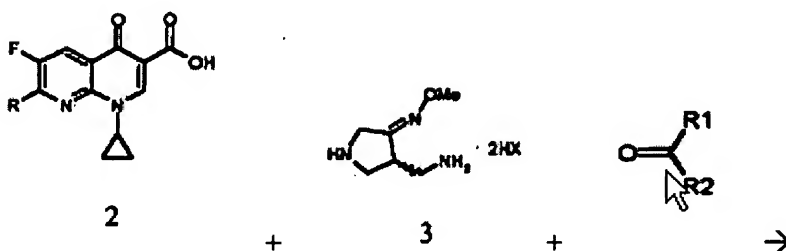
Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

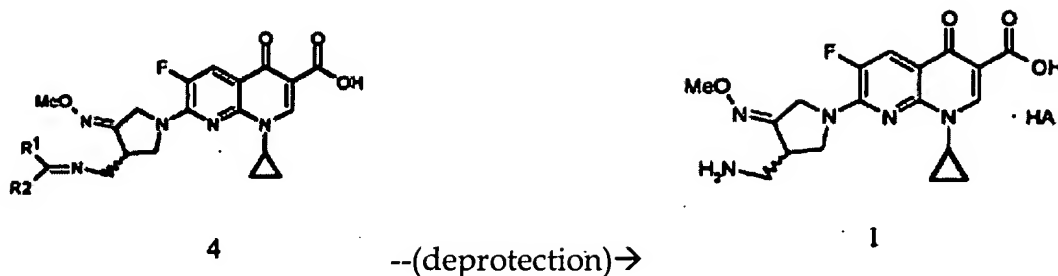
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hong (US Patent #5869670) in view of Khomutov.

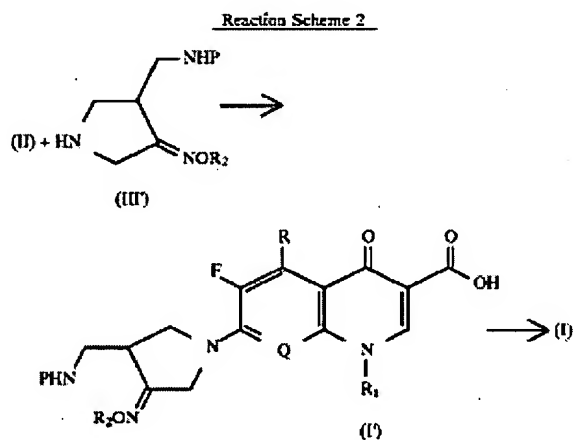
The instant claims are drawn to the process of



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Wherein 2+3+5 in water, an organic solvent or mixed solvent in the presence of an organic base \rightarrow 4 and then adding HA (acid) in water, an organic solvent or mixed solvent to make \rightarrow 1. The HX of formula 3 is trifluoroacetic acid or paratoluenesulfonic acid and HA is an organic or inorganic acid (claim 1).



Hong teaches

wherein P is a protecting group

(col 11 line 44: trifluoroacetyl & col 11 line 45 has paratoluenesulfonyl) of claim 1 page 4 lines 9 and 10 of instant application. This reaction can be done in the presence of a solvent (col 10 line 37) with the addition of a suitable base (col 10 line 39). The solvent can be acetonitrile (col 10 line 45) which is mirrored in the instant claim 4. The acid acceptor preferably used include triethylamine, diisopropylethylamine, and 1,8-diazabicyclo [5.4.0]undec-7-ene (col 10 lines 59-65) which are specifically claimed in the

instant claim 5. Hong teaches (col 11 lines 50-col 12 line 20) that the protecting group present can be removed by the use of an acid (organic or inorganic...col 11 lines 57 & 59) at a temperature of 0-130C. The temperature range of Hong encompasses the claimed temperature range of the instant claim 9. There is no mention of a recrystallization step in Hong.

Khomutov does teach the different cleavage steps by acid hydrolysis is well known and established in the art.

It would have been obvious to combine the process of Hong with the cleavage steps of Khomutov to obtain the gemifloxacin product. Rationale: The combination of common and well-known cleavage reaction with an established process to make gemifloxacin (as taught by Hong) to obtain gemifloxacin (the expected product) is well within the skill of the ordinary artisan.

Applicant argues that the preparation of a specific salt of the instant claims is different from the compound actually synthesized by Hong. However, by the above showing, the reaction steps are the same or similar. The expected product is given by the changes made in the reaction. Further applicant argues that the instant invention makes this specific salt form without impurities. However, the specific salt claimed in claim 1 is HA wherein HA is an organic acid or an inorganic acid and the claim 1 does not have a purity range in the claim.

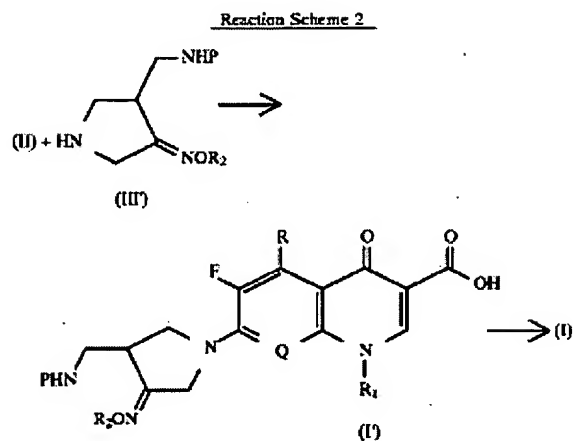
Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-13 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 5869670 in view of Khomutov. As stated in the above 103 rejection, Hong ('670) in view of Khomutov make the instant claims obvious. Hong teaches



wherein P is a protecting group (col 11 line44:

trifluoroacetyl & col 11 line 45 has paratoluenesulfonyl) of claim 1 page 4 lines 9 and 10 of instant application. This reaction can be done in the presence of a solvent (col 10 line 37) with the addition of a suitable base (col 10 line 39). The solvent can be acetonitrile (col 10 line 45) which is mirrored in the instant claim 4. The acid acceptor preferably used include triethylamine, diisopropylethylamine, and 1,8-diazabicyclo [5.4.0]undec-7-ene (col 10 lines 59-65) which are specifically claimed in the instant claim 5. Hong teaches (col 11 lines 50-col 12 line 20) that the protecting group present can be removed by the use of an acid (organic or inorganic...col 11 lines57 & 59) at a temperature of 0-130C. The temperature range of Hong encompasses the claimed temperature range of the instant claim 9. There is no mention of a recrystallization step in Hong.

Khomutov does teach the different cleavage steps by acid hydrolysis is well known and established in the art.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 11 is indefinite because it appears to be claiming a compound but then has a process step in the claim. Is claim 11 drawn to a compound? Or a further process step of claim 1? Correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 571-272-0694. The examiner can normally be reached on 730am-4pm, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



D. Margaret Seaman
Primary Examiner
Art Unit 1625

dms